

17.4 Instructions

Patients should be informed of the potential risks and benefits of Victoza and of alternative modes of therapy. Patients should also be informed about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and A_{1c} testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. During periods of stress such as fever, trauma, infection, or surgery, medication requirements may change and patients should be advised to seek medical advice promptly.

Patients should be advised that the most common side effects of Victoza are headache, nausea and diarrhea. Nausea is most common when first starting Victoza, but decreases over time in the majority of patients and does not typically require discontinuation of Victoza.

Physicians should instruct their patients to read the Patient Medication Guide before starting Victoza therapy and to reread each time the prescription is renewed. Patients should be instructed to inform their doctor or pharmacist if they develop any unusual symptom, or if any known symptom persists or worsens.

17.5 Laboratory Tests

Patients should be informed that response to all diabetic therapies should be monitored by periodic measurements of blood glucose and A_{1c} levels, with a goal of decreasing these levels towards the normal range. A_{1c} is especially useful for evaluating long-term glycemic control.

17.6 FDA-Approved Medication Guide

See separate leaflet.

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Victoza[®] is a registered trademark of Novo Nordisk A/S.

Victoza[®] is covered by US Patent Nos. 6,268,343, 6,458,924 and 7,235,627 and other patents pending.

Victoza[®] Pen is covered by US Patent Nos. 6,004,297, 6,235,004, 6,582,404 and other patents pending.

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MEDICATION GUIDE

Victoza[®] (VIC-tow-za)

(liraglutide [rDNA origin]) Injection

Read this Medication Guide and Patient Instructions for Use that come with Victoza before you start using Victoza and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment. If you have questions about Victoza after reading this information, ask your healthcare provider or pharmacist.

What is the most important information I should know about Victoza?

Serious side effects may happen in people who take Victoza, including:

1. **Possible thyroid tumors, including cancer.** During the drug testing process, the medicine in Victoza caused rats and mice to develop tumors of the thyroid gland. Some of these tumors were cancers. It is not known if Victoza will cause thyroid tumors or a type of thyroid cancer called medullary thyroid cancer in people. If medullary thyroid cancer occurs, it may lead to death if not detected and treated early. If you develop tumors or cancer of the thyroid, your thyroid may have to be surgically removed.
- Before you start taking Victoza, tell your healthcare provider if you or any of your family members have had thyroid cancer, especially medullary thyroid cancer, or Multiple Endocrine Neoplasia syndrome type 2. Do not take Victoza if you or any of your family members have medullary thyroid cancer, or if you have Multiple Endocrine Neoplasia syndrome type 2. People with these conditions already have a higher chance of developing medullary thyroid cancer in general and should not take Victoza.
- While taking Victoza, tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer.

2. Inflammation of the pancreas (pancreatitis), which may be severe and lead to death.

Before taking Victoza, tell your healthcare provider if you have had:

- pancreatitis
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

These medical conditions can make you more likely to get pancreatitis in general. It is not known if having these conditions will lead to a higher chance of getting pancreatitis while taking Victoza.

While taking Victoza:

Stop taking Victoza and call your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may happen with or without vomiting. The pain may be felt going from your abdomen through to your back. This type of pain may be a symptom of pancreatitis.

What is Victoza?

- Victoza is an injectable prescription medicine that may improve blood sugar (glucose) in adults with type 2 diabetes mellitus, and should be used along with diet and exercise.
- Victoza is not recommended as the first choice of medication for treating diabetes.
- Victoza is not insulin.
- It is not known if Victoza is safe and effective when used with insulin.
- Victoza is not for use in people with type 1 diabetes or people with diabetic ketoacidosis.
- It is not known if Victoza is safe and effective in children. Victoza is not recommended for use in children.

Who should not use Victoza?

Do not use Victoza if:

- you or any of your family members have a history of medullary thyroid cancer.
- you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). This is a disease where people have tumors in more than one gland in their body.

Talk with your healthcare provider if you are not sure if you have any of these conditions.

What should I tell my healthcare provider before using Victoza?

Before taking Victoza, tell your healthcare provider if you:

- have any of the conditions listed in the section “What is the most important information I should know about Victoza?”
- are allergic to liraglutide or any of the other ingredients in Victoza. See the end of this Medication Guide for a list of ingredients in Victoza.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- have or have had kidney or liver problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if Victoza will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking Victoza.
- are breastfeeding or plan to breastfeed. It is not known if Victoza passes into your breast milk. You and your healthcare provider should decide if you will take Victoza or breastfeed. You should not do both without talking with your healthcare provider first.

Tell your healthcare provider about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Victoza slows stomach emptying and can affect medicines that need to pass through the stomach quickly. Victoza may affect the way some medicines work and some other medicines may affect the way Victoza works. Tell your healthcare provider if you take other diabetes medicines, especially sulfonylurea medicines or insulin.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use Victoza?

- Use Victoza exactly as prescribed by your healthcare provider. Your dose should be increased after using Victoza for one week. After that, do not change your dose unless your healthcare provider tells you to.
- Victoza is injected 1 time each day, at any time during the day.
- You can take Victoza with or without food.
- Victoza comes in a prefilled pen.
- Your healthcare provider must teach you how to inject Victoza before you use it for the first time. If you have questions or do not understand the instructions, talk to your healthcare provider or pharmacist. See the Patient Instructions for Use that come with this Medication Guide for detailed information about the right way to use your Victoza pen.
- Pen needles are not included. You may need a prescription to get pen needles from your pharmacist. Ask your healthcare provider which needle size is best for you.
- When starting a new prefilled Victoza pen, you must follow the “First Time Use for Each New Pen” (see the detailed Patient Instructions for Use that comes with this Medication Guide). You only need to do this 1 time with each new pen. You should also do this if you drop your pen. If you do the “First Time Use for Each New Pen” before each injection, you will run out of medicine too soon.
- Inject your dose of Victoza under the skin (subcutaneous injection) in your stomach area (abdomen), upper leg (thigh), or upper arm, as instructed by your healthcare provider. **Do not inject into a vein or muscle.**
- If you take too much Victoza, call your healthcare provider right away. Too much Victoza may cause severe nausea and vomiting.
- Follow your healthcare provider’s instructions for diet, exercise, how often to test your blood sugar, and when to get your HbA_{1c} checked. If you stop using Victoza your blood sugar levels may increase. First talk to your healthcare provider if you want to stop taking Victoza.
- Your dose of diabetes medicines may need to be changed if your body is under certain types of stress. Tell your healthcare provider if you:
 - have fever
 - have trauma
 - have an infection
 - plan to have or have had surgery
- Never share your Victoza pen or needles with another person. You may give an infection to them, or get an infection from them.

What are the possible side effects of Victoza?

Victoza may cause serious side effects, including:

- See “What is the most important information I should know about Victoza?”
- **Low blood sugar (hypoglycemia).** Your risk for getting low blood sugar is higher if you take Victoza with another medicine that can cause low blood sugar, such as a sulfonylurea. In some people, the blood sugar may get so low that they need another person to help them. The dose of your sulfonylurea medicine may need to be lowered while you use Victoza. Signs and symptoms of low blood sugar may include:
 - shakiness
 - sweating
 - headache
 - drowsiness
 - weakness
 - dizziness
 - confusion
 - irritability

- hunger
- fast heartbeat
- feeling jittery

Talk to your healthcare provider about how to recognize and treat low blood sugar. Make sure that your family and other people who are around you a lot know how to recognize and treat low blood sugar.

Common side effects of Victoza include:

- headache
- nausea
- diarrhea

Nausea is most common when first starting Victoza, but decreases over time in most people as their body gets used to the medicine. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the side effects with Victoza. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Victoza?

Before use:

- Store your new, unused Victoza pen in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not freeze Victoza or use Victoza if it has been frozen. Do not store Victoza near the refrigerator cooling element.

Pen in use:

- Store your Victoza pen for 30 days either at 59°F to 86°F (15°C to 30°C), or in a refrigerator at 36°F to 46°F (2°C to 8°C).
- When carrying the pen away from home, store the pen at a temperature between 59°F to 86°F (15°C to 30°C) and keep it dry.
- If Victoza has been exposed to temperatures above 86°F (30°C), it should be thrown away.
- Protect your Victoza pen from heat and sunlight.
- Keep the pen cap on when your Victoza pen is not in use.
- Use your Victoza pen within 30 days after the first day it is stored outside the refrigerator. After these 30 days, throw away your Victoza pen even if some medicine is left in the pen.
- Do not use Victoza after the expiration date printed on the carton.

Do not store the Victoza pen with the needle attached. Always safely remove and safely throw away the needle after each injection. This may help prevent contamination, infection and leakage. It also helps to make sure that you get the correct dose of Victoza. See the Patient Instructions for Use for information about how to dispose of used pen needles and used Victoza pens.

Keep your Victoza pen, pen needles, and all medicines out of the reach of children.

General information about Victoza

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Victoza for a condition for which it was not prescribed. Do not give Victoza to other people, even if they have the same symptoms you have. It may harm them. This Medication Guide summarizes the most important information you should know about using Victoza. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Victoza that is written for health professionals.

For more information, go to victoza.com or call 1-877-484-2869.

What are the ingredients in Victoza?

Active Ingredient: liraglutide

Inactive Ingredients: disodium phosphate dihydrate, propylene glycol, phenol and water for injection

Manufactured by:

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